

**UNCLASSIFIED**

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)</b>	DATE <b>February 2000</b>
---	------------------------------

<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>	<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>
---	--

COST <i>(In Thousands)</i>	FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	11205	16566	15259	14669	11281	10009	11037	Continuing	Continuing
D808 DoD Drug and Vaccine-Advanced Development	3559	5121	4635	4060	5062	5098	5097	Continuing	Continuing
D811 Military HIV Vaccine and Drug-Advanced Development	3340	2669	5751	4665	657	137	161	Continuing	Continuing
D836 Combat Medical Materiel-Advanced Development	3480	3974	4017	4186	4007	3973	4008	Continuing	Continuing
D837 Soldier System Protection-Advanced Development	826	878	856	1758	1555	801	1771	Continuing	Continuing
D853 Combat Trauma Patient Simulator	0	3924	0	0	0	0	0	0	3924

**A. Mission Description and Justification:** This program element (PE) funds the advanced development (AD) of medical materiel necessary to field an effective capability for counteracting infectious diseases, treating, diagnosing and evacuating combat casualties, and developing operational medical drugs and materiels. The PE funds AD of systems for medical protection against naturally occurring diseases and human immunodeficiency virus (HIV). This includes development and initial human testing of vaccines, prophylactics, and therapeutic drugs. Additionally, the PE supports AD of field medical equipment and drugs essential for combat casualty care on all battlefields and military operations other than war. Systems include resuscitators, blood substitutes, advanced sensors and diagnostic algorithms, field x-ray, field production of medical grade oxygen, intensive care delivery platforms and litters, and hemostatic dressing. The PE also funds AD of systems that provide enhancement of or protection against physiological and psychological factors affecting cognitive and physical performance imposed by military systems, combat operations or the environment. This program is primarily managed by the U.S. Army Medical Research and Materiel Command.

UNCLASSIFIED

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)</b>	DATE <b>February 2000</b>
---	------------------------------

BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>	PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>
--	---

<b>B. Program Change Summary</b>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget ( <u>FY 2000/2001</u> PB)	11329	12723	12235
Appropriated Value	11414		
Adjustments to Appropriated Value			
a. Congressional General Reductions	-85		
b. SBIR / STTR	-243		
c. Omnibus or Other Above Threshold Adjustments			
d. Below Threshold Reprogramming	165		
e. Rescissions	-46		
Adjustments to Budget Years Since <u>FY 2000/2001</u> PB			+3096
Current Budget Submit ( <u>FY 2001</u> PB)	11205	16566	15259

Change Summary Explanation: Funding – FY 2001: Funds realigned from 0604807A, project 812, Military HIV Vaccines and Drug Development to 0603807A, project 811, Military HIV Vaccines and Drug Development. This action was necessary to align dollars to the stage of HIV research and in anticipation of an HIV vaccine to reach the final stages of the acquisition process.

**UNCLASSIFIED**

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)							DATE February 2000					
BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>				PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>				PROJECT <b>D808</b>				
COST (In Thousands)				FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D808 DoD Drug and Vaccine-Advanced Development				3559	5121	4635	4060	5062	5098	5097	Continuing	Continuing
<p><b>A. <u>Mission Description and Justification:</u></b> This project funds program definition and risk reduction of candidate medical countermeasures such as vaccines and drugs through safety, immunogenicity, and small-scale efficacy testing in volunteers against naturally occurring infectious diseases of mission-degrading or mission-aborting potential. Work performed in laboratories and among troop populations is directed to prevention, diagnosis, and treatment of viral, bacterial, and parasitic disease to prevent casualties, sustain operational performance, and minimize deaths and disability of armed forces during military operations. Some major contractors are Southern Research Institute, Birmingham AL; South Florida Research Institute, Miami, FL; Institute of Biology for the Army, Rio de Janeiro, Brazil; and Kenya Medical Research Institute, Nairobi, Kenya.</p> <p><b>FY 1999 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 1834 Completed Phase 2 clinical trial of RTS,S (TRAP) malaria vaccine.</li> <li>• 3 Filed an Investigational New Drug application for the reformulated liquid <i>Leishmania</i> skin test antigen.</li> <li>• 92 Conducted Phase 1 study with reformulated <i>Leishmania</i> skin test antigen.</li> <li>• 142 Continued Phase 2 safety and efficacy field trial for Paromomycin topical antileishmanial cream in Colombia.</li> <li>• 274 Started first year of Phase 1/2 safety and immunogenicity field trial for <i>Shigella flexneri</i> vaccine in Bangladesh.</li> <li>• 142 Completed Phase 1 safety study for <i>Shigella flexneri</i> vaccine in Bangladesh.</li> <li>• 50 Conducted Milestone (MS) I In-Process Review (IPR) for the hepatitis E vaccine program.</li> <li>• 368 Completed dose ranging study (Ghana) for long-term prophylaxis for Tafenoquine, an antimalarial drug.</li> <li>• 67 Conducted a meeting with the Food and Drug Administration (FDA): Endorsed a “fast track” drug development application for Tafenoquine.</li> <li>• 587 Initiated 2-year rat carcinogenicity study for Tafenoquine.</li> </ul> <p>Total 3559</p> <p><b>FY 2000 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 892 Conduct Phase 1 study to refine dose regimen for RTS,S (TRAP) malaria vaccine.</li> <li>• 148 Complete Phase 2 safety and immunogenicity field trial for Paromomycin topical antileishmanial cream in Colombia.</li> <li>• 30 Conduct market survey for co-development partner for Paromomycin topical antileishmanial cream.</li> <li>• 132 Initiate Phase 2 efficacy field trial for Paromomycin topical antileishmanial cream in France.</li> <li>• 82 Start program for clinical diagnostic assay for <i>Leishmania</i>.</li> </ul>												
Project D808				Page 3 of 18 Pages				Exhibit R-2A (PE 0603807A)				

UNCLASSIFIED

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)		DATE February 2000
BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
<b>4 - Demonstration and Validation</b>	<b>0603807A Medical Systems - Advanced Development</b>	<b>D808</b>
<ul style="list-style-type: none"> <li>• 491 Continue Phase 1/2 safety and efficacy field trials for <i>Shigella flexneri</i> vaccine in Bangladesh.</li> </ul> <p><b>FY 2000 Planned Program: (continued)</b></p> <ul style="list-style-type: none"> <li>• 55 Complete Phase 1b clinical trials in Nepal for the hepatitis E vaccine program.</li> <li>• 801 Initiate Phase 2 clinical trials in Nepal for the hepatitis E vaccine program.</li> <li>• 50 Conduct a MS II for Tafenoquine antimalarial drug.</li> <li>• 50 Conduct a MS I IPR for the dengue tetravalent vaccine program.</li> <li>• 445 Initiate development of human challenge model for the clinical evaluation of the efficacy of dengue tetravalent vaccines.</li> <li>• 219 Initiate sequencing and cloning of dengue types 2, 3, and 4 monovalent vaccines.</li> <li>• 50 Conduct a MS I IPR for the dengue rapid diagnostic program.</li> <li>• 207 Conduct a MS I IPR and initiate lethal ovitrap for dengue vectors program.</li> <li>• 50 Conduct a MS I IPR for rapid detection of <i>Plasmodium</i> infection in mosquitoes program.</li> <li>• 50 Start scrub typhus diagnostic kit program.</li> <li>• 436 Conduct a MS I IPR and initiate a program for camouflage face paint with insect repellent and reduced infrared signature.</li> <li>• 407 Conduct a MS I IPR and initiate malaria rapid diagnostic device program.</li> <li>• 50 Conduct a MS I IPR on artelinic acid, an antimalarial drug.</li> <li>• 182 Prepare Investigational New Drug application submission on artelinic acid.</li> <li>• 182 Initiate Phase 1 safety trials on artelinic acid.</li> <li>• 112 Small Business Innovative Research/Small Business Technology Transfer Research Programs.</li> </ul> <p>Total 5121</p> <p><b>FY 2001 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 50 Complete Phase 1 study to refine dose regimen for RTS,S malaria vaccine.</li> <li>• 124 Conduct Phase 2 efficacy study on <i>Leishmania</i> skin test antigen.</li> <li>• 50 Complete Phase 2 efficacy field trial for Paromomycin topical antileishmanial cream in France.</li> <li>• 193 Conduct developmental testing of prototype clinical diagnostic assay for <i>Leishmania</i>.</li> <li>• 50 Complete Phase 1/2 safety and immunogenicity field trials for <i>Shigella flexneri</i> vaccine in Bangladesh.</li> <li>• 308 Conduct expanded Phase 2 safety and efficacy field trial for <i>Shigella flexneri</i> vaccine in Bangladesh.</li> <li>• 50 Conduct a MS II IPR for <i>Shigella flexneri</i> vaccine.</li> <li>• 772 Complete the Phase 2 clinical trial in Nepal for the hepatitis E vaccine program.</li> <li>• 418 Start Phase 2 field trials for dengue tetravalent vaccine.</li> <li>• 215 Conduct developmental testing of prototype dengue rapid diagnostic device.</li> </ul>		
Project D808	Page 4 of 18 Pages	Exhibit R-2A (PE 0603807A)

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>	DATE <b>February 2000</b>
--	------------------------------

<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>	<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>	<b>PROJECT</b> <b>D808</b>
---	--	-------------------------------

- 104 Continue lethal ovitrap for dengue vectors development program.
  
- FY 2001 Planned Program: (continued)**
- 50 Complete development of human challenge model for the clinical evaluation of the efficacy of dengue tetravalent vaccines.
- 173 Complete sequencing and cloning of dengue types 2, 3, and 4 monovalent vaccines.
- 76 Continue developmental testing of a prototype kit for the rapid detection of *Plasmodium* infected mosquitoes and conduct a MS II IPR.
- 465 Conduct developmental testing of prototype scrub typhus diagnostic device.
- 215 Conduct developmental testing and a MS II IPR of camouflage face paint with insect repellent and reduced infrared signature.
- 50 Conduct a MS II IPR for camouflage face paint with insect repellent and reduced IR signature.
- 325 Conduct developmental testing and a MS II IPR of prototype malaria rapid diagnostic device.
- 174 Continue Phase 1 safety trials on artelinic acid, an antimalarial drug.
- 174 Initiate Phase 2 efficacy trial on artelinic acid.
- 52 Advertise for Cooperative Research and Development Agreement partner on artelinic acid.
- 290 Start first year of Phase 1/2 safety and immunogenicity field trials for *Shigella sonnei* vaccine.
- 50 Conduct a MS I IPR for *Shigella sonnei* vaccine.
- 207 Conduct a MS I IPR and initiate Japanese encephalitis vaccine (improved) program.
  
- Total 4635

**B. Other Program Funding Summary:** Not applicable.

**C. Acquisition Strategy:** Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure.

<b>D. Schedule Profile</b>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
RTS,S malaria vaccine							MS II 1QTR		
Leishmania Skin Test						MS II 1QTR			
Camouflage face paint				MS I 1QTR	MS II 4QTR				
Artelinic acid				MS I 3QTR			MS II 1QTR		

UNCLASSIFIED

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>	DATE <b>February 2000</b>
--	------------------------------

<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>	<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>	<b>PROJECT</b> <b>D808</b>
---	--	-------------------------------

<b>D. Schedule Profile</b>	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
<i>Shigella flexneri</i>					MS II 3QTR				
Paromomycin							MS II 1QTR		
Tafenoquine antimalarial				MS II 2QTR					
Dengue rapid diagnostic device				MS I 4QTR			MS II 4QTR		
Hepatitis E vaccine			MS I 4QTR			MS II 3QTR			
Dengue tetravalent vaccine				MS I 2QTR		MS II 3QTR			
Malaria Rapid Diagnostic Device				MS I 1QTR	MS II 4QTR				
Lethal ovitrap for dengue-infected mosquitoes				MS I 3QTR					
Detection of <i>Plasmodium</i> infected mosquitoes				MS I 4QTR	MS II 4QTR				
<i>Shigella sonnei</i> vaccine					MS I 2QTR				
Japanese encephalitis vaccine (improved)					MS I 2QTR		MS II 2QTR		
Scrub typhus diagnostic device				MS I 2QTR		MS II 4QTR			
Clinical diagnostic assay for Leishmania				MS I 4QTR					

**UNCLASSIFIED**

<b>ARMY RDT&amp;E COST ANALYSIS (R-3)</b>										DATE <b>February 2000</b>		
<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>				<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>						<b>PROJECT</b> <b>D808</b>		
<b>I. Product Development</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Total PYs Cost</b>	<b>FY 1999 Cost</b>	<b>FY 1999 Award Date</b>	<b>FY 2000 Cost</b>	<b>FY 2000 Award Date</b>	<b>FY 2001 Cost</b>	<b>FY 2001 Award Date</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
a. No product/contract costs greater than \$1M individually			204	286		412		373		Continue	1275	
b. Subtotal Product Development:			204	286		412		373			1275	
<b>II. Support Costs</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Total PYs Cost</b>	<b>FY 1999 Cost</b>	<b>FY 1999 Award Date</b>	<b>FY 2000 Cost</b>	<b>FY 2000 Award Date</b>	<b>FY 2001 Cost</b>	<b>FY 2001 Award Date</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
a. No product/contract costs greater than \$1M individually			103	179		259		233		Continue	774	
b. Subtotal Support Costs:			103	179		259		233			774	
<b>III. Test and Evaluation</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Total PYs Cost</b>	<b>FY 1999 Cost</b>	<b>FY 1999 Award Date</b>	<b>FY 2000 Cost</b>	<b>FY 2000 Award Date</b>	<b>FY 2001 Cost</b>	<b>FY 2001 Award Date</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
a. No product/contract costs greater than \$1M individually			1278	2236		3214		2913		Continue	9641	
b. Subtotal Test and Evaluation:			1278	2236		3214		2913			9641	

**UNCLASSIFIED**

ARMY RDT&E COST ANALYSIS (R-3)										DATE February 2000		
BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>				PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>						PROJECT <b>D811</b>		
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			478	858		1236		1116		Continue	3688	
b. Subtotal Management Services:			478	858		1236		1116			3688	
Project Total Cost:			2063	3559		5121		4635			15378	

**UNCLASSIFIED**

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>							DATE <b>February 2000</b>			
<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>				<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>				<b>PROJECT</b> <b>D811</b>		
<i>COST (In Thousands)</i>	FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost	
D811 Military HIV Vaccine and Drug-Advanced Development	3340	2669	5751	4665	657	137	161	Continuing	Continuing	
<p><b>A. <u>Mission Description and Justification:</u></b> This project funds Congressionally mandated, militarily relevant human immunodeficiency virus (HIV) research for demonstration and validation of candidate vaccines and drugs through safety, immunogenicity, and small-scale efficacy testing and behavioral intervention in volunteers. Efforts are directed to answer militarily unique needs affecting manning, mobilization, and deployment.</p> <p><b>FY 1999 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 3340 Conducted Phase 2 efficacy field trials for GP120 recombinant protein HIV vaccine.</li> </ul> <p>Total 3340</p> <p><b>FY 2000 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 1825 Conduct first year of Phase 2 downselection study of GP120 and GP160 recombinant protein HIV vaccines.</li> <li>• 50 Conduct a MS I/II IPR for GP120 recombinant protein HIV vaccine.</li> <li>• 50 Conduct a MS I IPR for GP160.</li> <li>• 672 Conduct dose ranging study for GP120 recombinant protein HIV vaccine.</li> <li>• 72 Small Business Innovative Research/Small Business Technology Transfer Research Programs.</li> </ul> <p>Total 2669</p> <p><b>FY 2001 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 5751 Continue Phase 2 downselection study of GP120 and GP160 recombinant protein HIV vaccines.</li> </ul> <p>Total 5751</p> <p><b>B. <u>Other Program Funding Summary:</u></b> Not applicable.</p> <p><b>C. <u>Acquisition Strategy:</u></b> Test and evaluate commercially developed vaccine candidates in government-managed trials.</p>										
Project D811			Page 9 of 18 Pages			Exhibit R-2A (PE 0603807A)				

UNCLASSIFIED

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>	DATE <b>February 2000</b>
--	------------------------------

BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>	PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>	PROJECT <b>D811</b>
--	---	------------------------

<b>D. Schedule Profile</b>	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
GP120 recombinant protein HIV vaccine					MS I/II 1QTR					
GP160 HIV vaccine					MS I 1QTR		MS II 1QTR			
Combined HIV Vaccine								MS I 1QTR		

**UNCLASSIFIED**

<b>ARMY RDT&amp;E COST ANALYSIS (R-3)</b>	DATE <b>February 2000</b>
---	------------------------------

<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>	<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>	<b>PROJECT</b> <b>D811</b>
---	--	-------------------------------

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. Product Development			3340	2669		5751		Continue	11760	
Subtotal Product Development:			3340	2669		5751		Continue	11760	

II. Support Costs: Not applicable

III. Test and Evaluation: Not applicable

IV. Management Services: Not applicable

Project Total Cost:			3340	2669		5751		Continue	11760	
---------------------	--	--	------	------	--	------	--	----------	-------	--

**UNCLASSIFIED**

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)							DATE February 2000			
BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>				PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>				PROJECT <b>D836</b>		
COST ( <i>In Thousands</i> )	FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost	
D836 Combat Medical Materiel-Advanced Development	3480	3974	4017	4186	4007	3973	4008	Continuing	Continuing	
<p><b>A. <u>Mission Description and Justification:</u></b> The project supports advanced development of new and improved systems essential for battlefield casualty care, patient transport and evacuation, and return to duty in support of special contingency and conventional force operations. Primary civilian contractors are University of Illinois, Chicago, IL; United Defense Limited Partnership, San Jose, CA; Mission Medical; American Red Cross; and Northrup Grumman.</p> <p><b>FY 1999 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 2036 Evaluated Armored Medical Evacuation Vehicle (AMEV) in National Training Center Rotation 99-05 and conducted a Milestone (MS) I/II In-Process Review (IPR).</li> <li>• 290 Developed prototype Warrior Medic variant system and conducted a MS 0/I IPR.</li> <li>• 126 Initiated protocol for Food and Drug Administration (FDA) approval process of Thawed Blood Processing System (TBPS), finalized design of device, and fabricated two prototypes in accordance with FDA current Good Manufacturing Practices (cGMP) procedures.</li> <li>• 823 Established Acquisition Plan for Hemostatic Dressing and conducted animal model trials on nine prototype dressings, furnished by potential corporate partners, to select dressings, which will be further developed.</li> <li>• 28 Continued technology watch and evaluation of Ceramic Oxygen Generator technologies.</li> <li>• 139 Continued development and refinement of Critical Care System for Trauma and Transport (CSTAT) device to include air worthiness certification.</li> <li>• 38 Constructed lightweight litter using advanced composite materials.</li> </ul> <p>Total 3480</p> <p><b>FY 2000 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 1671 Complete Engineering and Manufacturing Development (EMD) vehicle and conduct Limited User Test for AMEV.</li> <li>• 62 Conduct technology cost-benefit trade-off analysis, a MS I/II IPR, and initiate formal acquisition program for CSTAT device.</li> <li>• 326 Complete Warrior Medic variant design and qualification testing.</li> <li>• 1058 Complete animal model evaluation, conduct a MS I IPR, and secure commercial partner for product development of the Hemostatic Dressing.</li> <li>• 120 Conduct a MS I/II for TBPS and complete in vitro and in vivo testing necessary for FDA approval.</li> <li>• 326 Initiate development of Next Generation Jet Injector for needle-less injection of drugs and vaccines.</li> <li>• 104 Complete user testing of Special Operations Resuscitation and Surgical Station and preparation of the technical data package.</li> <li>• 97 Initiate Ceramic Oxygen Generation development program to develop a lightweight, high purity oxygen generator for field use.</li> </ul>										
Project D836			Page 12 of 18 Pages				Exhibit R-2A (PE 0603807A)			

UNCLASSIFIED

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>	DATE <b>February 2000</b>
--	------------------------------

<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>	<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>	<b>PROJECT</b> <b>D836</b>
---	--	-------------------------------

**FY 2000 Planned Program: (continued)**

- 52 Evaluate the use of commercial Medical Waste Disposal Systems in field military hospitals.
  - 77 Conduct a MS 0/I IPR and initiate advanced development efforts for a 10-week red blood cell storage solution.
  - 81 Small Business Innovative Research/Small Business Technology Transfer Research Programs.
- Total 3974

**FY 2001 Planned Program:**

- 240 Conduct operational testing and a MS III IPR for the CSTAT device.
  - 404 Conduct development tests of the Next Generation Jet Injector and a MS I IPR.
  - 227 Prepare initial operational test and evaluation for Warrior Medic program.
  - 65 Prepare documentation for FDA submission for TBPS.
  - 1500 Begin low rate initial production and conduct production qualification test for AMEV.
  - 1200 Continue safety and efficacy trials for Hemostatic Dressing, initiate human trials using elective surgery, and conduct an MS II.
  - 112 Continue development of the Ceramic Oxygen Generation System to include testing potential product for durability in the field medical environment and conduct a MS I IPR.
  - 74 Complete user testing of a Field Medical Waste Disposal System.
  - 120 Complete FDA-required in vivo and in vitro testing of a solution capable of maintaining viable red blood cells for a 10-week period.
  - 75 Conduct an MS II IPR for 10-week Blood
- Total 4017

**B. Other Program Funding Summary:** Not applicable.

**C. Acquisition Strategy:** Evaluate commercially developed materiel in government-managed tests for hardening or other modification.

<b>D. Schedule Profile</b>	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Warrior Medic				MS 0/I 4QTR				MS II/III 1QTR		
CSTAT					MS I/II 3QTR	MS III 4QTR				
Hemostatic Dressing					MS I 2QTR	MS II 4QTR				

**UNCLASSIFIED**

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>								DATE <b>February 2000</b>		
BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>					PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>				PROJECT <b>D836</b>	
<b>D. Schedule Profile</b>	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
AMEV				MS I/II 3QTR						
Ceramic Oxygen Generator System						MS I 4QTR			MS II 3QTR	
Next Generation Jet Injector						MS I 4QTR				
10-Week Blood					MS 0/I 3QTR	MS II 4QTR				
TBPS					MS I/II 3QTR					
Project D836			Page 14 of 18 Pages				Exhibit R-2A (PE 0603807A)			

**UNCLASSIFIED**

<b>ARMY RDT&amp;E COST ANALYSIS (R-3)</b>										DATE <b>February 2000</b>		
<b>BUDGET ACTIVITY</b> <b>4 - Demonstration and Validation</b>				<b>PE NUMBER AND TITLE</b> <b>0603807A Medical Systems - Advanced Development</b>						<b>PROJECT</b> <b>D836</b>		
<b>I. Product Development</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Total PYs Cost</b>	<b>FY 1999 Cost</b>	<b>FY 1999 Award Date</b>	<b>FY 2000 Cost</b>	<b>FY 2000 Award Date</b>	<b>FY 2001 Cost</b>	<b>FY 2001 Award Date</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
a. AMEV	MIPR	PM Bradley, Warren, MI	1990	1010	Nov 98	1204		1300		Continue	5504	
b. No other contract exceeds \$1M						200		1796			1996	
Subtotal Product Development:			1990	1010		1404		3096			7500	
II. Support Costs: No product/contract costs greater than \$1M individually												
III. Test and Evaluation: No product/contract costs greater than \$1M individually												
<b>IV. Management Services</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Total PYs Cost</b>	<b>FY 1999 Cost</b>	<b>FY 1999 Award Date</b>	<b>FY 2000 Cost</b>	<b>FY 2000 Award Date</b>	<b>FY 2001 Cost</b>	<b>FY 2001 Award Date</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
a. No product/contract costs greater than \$1M individually			1618	2470		2570		921		Continue	7579	
Subtotal Management Services:			1618	2470		2570		921			7579	
<b>Project Total Cost:</b>			3608	3480		3974		4017			15079	

**UNCLASSIFIED**

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)							DATE February 2000			
BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>				PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>				PROJECT <b>D837</b>		
COST (In Thousands)	FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost	
D837 Soldier System Protection-Advanced Development	826	878	856	1758	1555	801	1771	Continuing	Continuing	
<p><b>A. <u>Mission Description and Justification:</u></b> This project supports demonstration and validation of preventive medicine materiel including devices, pharmacologicals, and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions. Focus is on reduction in the incidence of personnel losses due to preventable disease and non-battle injuries through development of environmental and physiological performance monitors and other preventive medicine countermeasures.</p> <p><b>FY 1999 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 31 Provided consultation on the Warfighter Physiological Status Monitor (WPSM).</li> <li>• 76 Developed required programmatic and technical documentation and conducted correspondence for Milestone (MS) 0/I In-Process Review (IPR) for Warrior Medic Program.</li> <li>• 374 Developed prototype Warrior Medic variant system.</li> <li>• 145 Provided system engineering support for system integration with Force XXI Battle Command – Brigade and Below (FBCB2) and Global Combat Support System (GCSS).</li> <li>• 200 Prepared and released request for proposals for manufacturing of Leishmania Skin Test Antigen (LSTA).</li> </ul> <p>Total 826</p> <p><b>FY 2000 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 41 Prepare acquisition documents for a MS 0 IPR for the WPSM and continue development efforts.</li> <li>• 814 Continue contract funding for required Investigational New Drug application sections and manufacturing of LSTA kits.</li> <li>• 23 Small Business Innovative Research/Small Business Technology Transfer Research Programs.</li> </ul> <p>Total 878</p> <p><b>FY 2001 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 31 Continue refinement of the WPSM.</li> <li>• 825 Provide for manufacture of LSTA kits for Phase 1 dose ranging safety and sensitivity clinical trial and conduct a MS II IPR. Initiate development efforts for a Drinking Water Microbiological Assay to allow rapid confirmation of contaminated drinking water</li> </ul> <p>Total 856</p>										
Project D837			Page 16 of 18 Pages				Exhibit R-2A (PE 0603807A)			

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>	DATE <b>February 2000</b>
--	------------------------------

BUDGET ACTIVITY <b>4 - Demonstration and Validation</b>	PE NUMBER AND TITLE <b>0603807A Medical Systems - Advanced Development</b>	PROJECT <b>D837</b>
--	---	------------------------

**B. Other Program Funding Summary:** Not applicable.

**C. Acquisition Strategy:** Test and evaluate materiel in government-managed trials to meet fielding requirements.

<b>D. Schedule Profile</b>	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
LSTA						MS II 4QTR				
WPSM					MS 0 1QTR					

**UNCLASSIFIED**

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)							DATE February 2000			
BUDGET ACTIVITY 4 - Demonstration and Validation			PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development					PROJECT D837		
COST (In Thousands)	FY 1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost	
D853 Combat Trauma Patient Simulator	0	3924	0	0	0	0	0	0	3924	
<p><b>A. <u>Mission Description and Justification:</u></b> By Congressional direction, the purpose of this program is to develop prototypes of and demonstrate an integrated medical simulation system that will enhance "home station" training of battlefield health care providers at the individual and unit levels.</p> <p><b>FY 1999 Accomplishments:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 3818 Collaborate with STRICOM to conduct concept exploration, functional testing, evaluation, and demonstration of a medical/surgical simulation system that will enable planning and rehearsal of realistic combat casualty care procedures and ensure the skill currency of "first responders (e.g. combat medics, physician assistants)" and combat surgeons.</li> <li>• 106 Small Business Innovative Research/Small Business Technology Transfer Research Programs.</li> </ul> <p>Total 3924</p> <p><b>FY 2001 Planned Program:</b> Continue concept exploration, functional testing, evaluation, and demonstration of a medical/surgical simulation system that will enable planning and rehearsal of realistic combat casualty care procedures and ensure the skill currency of "first responders (e.g. combat medics, physician assistants)" and combat surgeons.</p> <p><b>B. <u>Other Program Funding Summary:</u></b> Not applicable.</p> <p><b>C. <u>Acquisition Strategy:</u></b> Test and evaluate commercially developed vaccine candidates in government-managed trials.</p> <p><b>D. <u>Schedule Profile:</u></b> Not applicable.</p>										
Project D837			Page 18 of 18 Pages				Exhibit R-2A (PE 0603807A)			